

Application No.: 10/803,153
Amendment and Response dated May 27, 2008
Reply to Office Action of February 26, 2008
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Remarks/Arguments:

Introduction

Claim 1, 4, 9 and 11 have been amended to describe that at least two thin wall graft members completely overlap a preselected length of a patient's body lumen at a desired site, in particular overlapping a lesion in the body lumen. Claims 14 and 17 have been non-narrowing amended as to the form of the claims.

No new matter is introduced with these claim amendments.

Entry of the claim amendments is respectfully requested.

Section 112 Rejections

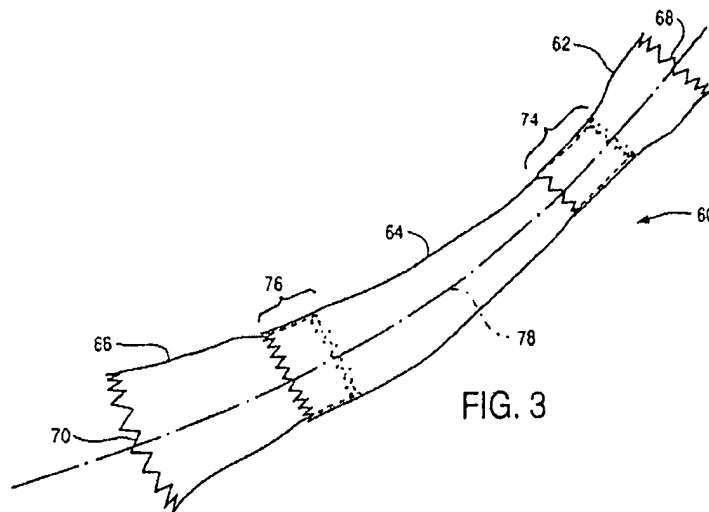
Claims 9-13 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking support in the specification. Claims 1 and 4-8 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. Applicant respectfully submits that the amendments to claims 1, 4, 9 and 11 obviate the Section 112 rejections.

Reconsideration and withdrawal of the section 112 rejections are respectfully requested.

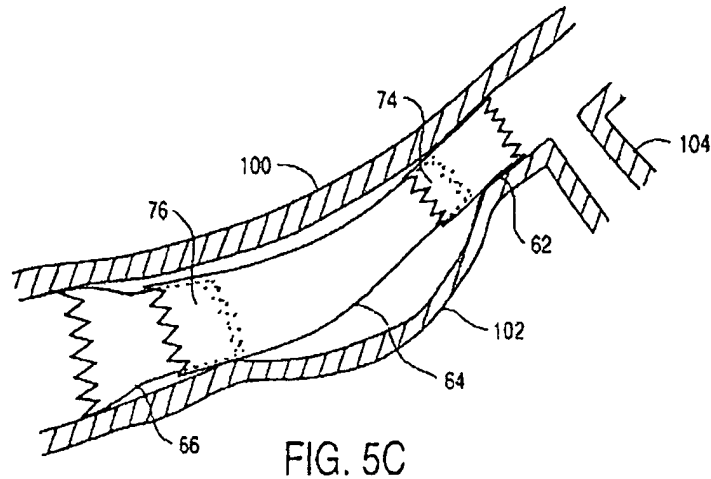
Section 102 Rejections

A) Claims 1, 4, 5, 7, 8, 17 and 18 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent No. 6,123,722 to Fogarty et al. (hereinafter "Fogarty"). Applicant respectfully traverses.

The graft modules of Fogarty are deployed in a slightly overlapping manner to provide a deployed modular graft capable of supporting a bodily lumen. (See, e.g., Fogarty). Fogarty clearly fails to disclose the overlapping feature as claimed. For example, prosthetic module 64 slightly overlaps the proximal cuff module 66 at a narrow region 76. In a similar fashion, the distal cuff module 62 slightly overlaps the prosthetic module 64 at narrow region 74. For convenience of the examiner, Fig. 3 of Fogarty is reproduced below, as follows:



Moreover, Fogarty clearly fails to disclose that its graft modules may be completely overlapped in the deployed state over a desired bodily site, for example an aneurysm, to be supported. As depicted in Fig. 5C, only the prosthetic module 64 overlaps any substantial longitudinal extent of aneurysm 102. The cuffs 62 and 66 do not substantially overlap the aneurysm 102. Indeed, the overlap region 76 is depicted as being located prior to the aneurysm 102. For convenience of the examiner, Fig. 5C of Fogarty is reproduced below, as follows:



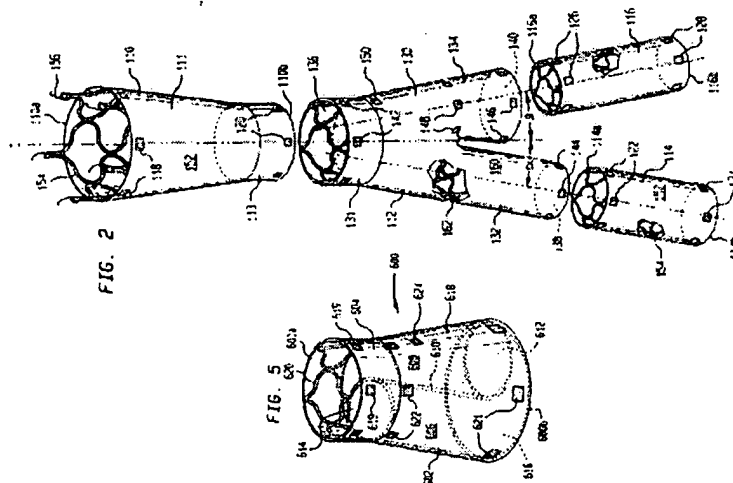
As Fogarty fails to disclose whether a plurality of its different components may be completely overlapping a diseased site in a bodily lumen, i.e., at least two of Fogarty's modular members completely overlapping a lesion or the like within a body lumen, the Examiner must then properly apply an inherency argument to the missing descriptive matter of Fogarty. To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *Crown Oper. Int'l Inc. v. Solutia Inc.*, 289 F.3d 1367, 62 U.S.P.Q.2d 1917 (Fed. Cir. 2002). Further, inherency may not be established by probabilities or possibilities, and the mere fact that a certain thing may result from a given set of circumstances is not sufficient for a *prima facie* case of anticipation. *Scaltech Inc. v. Retec/Tetra L.L.C.*, 153 F.3d 1193, 51 U.S.P.Q.2d 1055 (Fed. Cir. 1999). Occasional results are not inherent. *Mehl/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1365, 52 U.S.P.Q.2d 1303, 1306 (Fed. Cir. 1999).

As the recited overlapping of graft components are not necessarily and unambiguously derived from the disclosure of Fogarty, Fogarty fails to disclose each and every limitation as set forth in claims 1, 4, 5, 7, 8, 17.

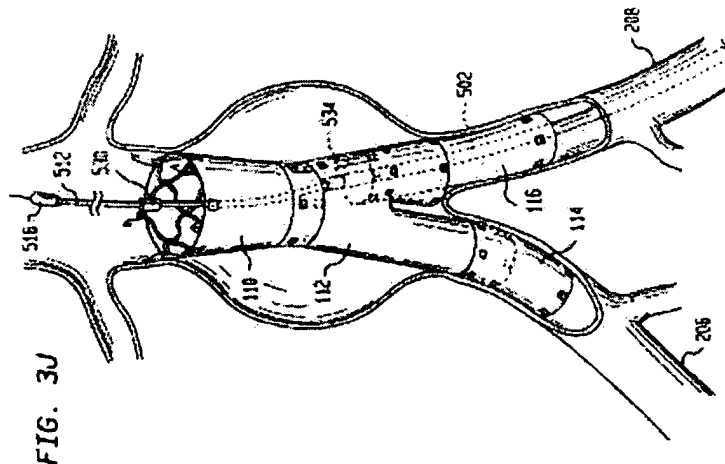
Therefore, reconsideration and withdrawal of the rejection of claims 1, 4, 5, 7, 8, 17 and 18 over Fogarty under 35 U.S.C. §102(e) are respectfully requested.

B) Claims 1, 4, 5, 7, 8, 14, 15, 17 and 18 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent No. 5,683,449 to Marcade (hereinafter "Marcade"). Applicant respectfully traverses.

The examiner alleges that the component members of Marcade overlap within the claimed limitation of the subject claims. Applicant respectfully traverses. Marcade is directed to a modular bifurcated graft 100. The bifurcated graft includes a primary graft 110 and two secondary grafts or legs 114, 116. A base member 112 in the shape of a "Y" is used to connect the primary graft 110 and the legs 114, 116, as depicted in Fig. 2. Alternatively, a base member 600, which has a frustoconical shape as depicted in Fig. 5, may be used to connect the primary graft 110 and the legs 114, 116. For convenience of examiner these figures are reproduced below, as follows:



None of the components 100, 112 (or 600), 114 and 116 of Marcade, however, completely overlay the diseased portion of a bodily lumen. Such an incomplete overlapping is clearly depicted in Fig. 3J of Marcade, which is reproduced below for the convenience of the examiner, as follows:



As Marcade fails to disclose whether a plurality of its different components may be completely overlapping a diseased site in a bodily lumen, i.e., at least two of Marcade's modular members completely overlapping a lesion or the like within a body lumen, the Examiner must then properly apply an inherency argument to the missing descriptive matter of Marcade. To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *Crown Oper. Int'l Inc. v. Solutia Inc.*, 289 F.3d 1367, 62 U.S.P.Q.2d 1917 (Fed. Cir. 2002). Further, inherency may not be established by probabilities or possibilities, and the mere fact that a certain thing may result from a given set of circumstances is not sufficient for a *prima facie* case of anticipation. *Scaltech Inc. v. Retec/Tetra L.L.C.*, 153 F.3d 1193, 51 U.S.P.Q.2d 1055 (Fed. Cir. 1999). Occasional results are not inherent. *Mehl/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1365, 52 U.S.P.Q.2d 1303, 1306 (Fed. Cir. 1999).

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As the recited overlapping of graft components are not necessarily and unambiguously derived from the disclosure of Marcade, Marcade fails to disclose each and every limitation as set forth in claims 1, 4, 5, 7, 8, 14, 15, 17 and 18.

Therefore, reconsideration and withdrawal of the rejection of claims 1, 4, 5, 7, 8, 14, 15, 17 and 18 over Marcade under 35 U.S.C. §102(e) are respectfully requested.

Section 103 Rejections

A) Claims 6, 9-13 and 16 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Fogarty. Applicant respectfully traverses.

The examiner acknowledges that each component member of Fogarty is a stent-graft and that Fogarty's grafts without the stents would not hold open a diseased portion of a body lumen, as follows:

[E]ach member is a stent-graft, and the graft members alone do not provide the support to the vessel, it is the stent that provided the support to the graft and to the vessel ... and therefore, all graft used alone would not provide sufficient strength to hold open the vessel. (Office Action dated February 26, 2008, page 4)

The very purpose, intent and function of the device of Fogarty is to hold open the diseased portion of a body lumen. Removal of the stent, as proposed by the examiner, would thusly destroy the very purpose, intent and function of Fogarty.

Moreover, removal of the stent, as acknowledged by the examiner, would make the device of Fogarty inoperable for its intended purpose. An inoperable reference, such as the modified device of Fogarty as proposed by the examiner, cannot form a basis for a *prima facie* case of obviousness. *In re Gordon et al.*, 221 U.S.P.Q. 1125, 1127 (CAFC 1984). Indeed, such an inoperable device as proposed by the examiner is a direct teaching away from the present invention. *Id.*

Further, any attempt to modify the teachings of Fogarty to suggest its graft modules may be completely overlapped is hindsight reconstruction. It is well established, however, that hindsight reconstruction of a reference does not present a *prima facie* case of obviousness, and any attempt at hindsight reconstruction using Applicant's disclosure is strictly prohibited. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445-46 (Fed. Cir. 1993).

Thus, Fogarty fails to teach or suggest the claimed features of independent claims of the subject application. Therefore, reconsideration and withdrawal of the rejections of claims 6, 9-13 and 16 are respectfully requested.

B) Claims 6, 9-13 and 16 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Marcade. Applicant respectfully traverses.

Marcade specifically describes that its main graft and legs are stent-grafts, as follows:

"Each of the grafts 110, 114 and 116 ... consists of a flexible outer layer 152 which is supported internally along substantially its entire length by an expandable stent 154...."
(Marcade, column 11, lines 58-60) (emphasis added)

Marcade also specifically describes that its connector or base is also a stent-graft, as follows:

"Base member 112 is similar in construction to grafts 110, 114 and 116, and includes a flexible outer layer 160 ... and an expandable generally Y-shaped stent 162 internally supports outer layer 160 along substantially its entire length, providing structural strength thereto...." (Marcade, column 14, lines 1-6) (emphasis added)

"[B]ase member 600 ... consists a flexible outer layer 618 which is supported internally along substantially its entire length by an expandable stent 620." (Marcade, column 19, lines 33-36) (emphasis added)

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Thus, all of the components of Marcade are stent-grafts where the stents provide the support for the grafts. The very purpose, intent and function of the devices of Marcade are to hold open the diseased portion of a body lumen. Removal of the stents, as proposed by the examiner, would thusly destroy the very purpose, intent and function of Marcade.

Moreover, removal of the stents would make the device of Marcade inoperable for its intended purpose. An inoperable reference, such as the modified device of Marcade as proposed by the examiner, cannot form a basis for a *prima facie* case of obviousness. *In re Gordon et al.*, 221 U.S.P.Q. 1125, 1127 (CAFC 1984). Indeed, such an inoperable device as proposed by the examiner is a direct teaching away from the present invention. *Id.*

Further, any attempt to modify the teachings of Marcade to suggest its grafts may be completely overlapped is hindsight reconstruction. It is well established, however, that hindsight reconstruction of a reference does not present a *prima facie* case of obviousness, and any attempt at hindsight reconstruction using Applicant's disclosure is strictly prohibited. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445-46 (Fed. Cir. 1993).

Thus, Marcade fails to teach or suggest the claimed features of independent claims of the subject application. Therefore, reconsideration and withdrawal of the rejections of claims 6, 9-13 and 16 are respectfully requested.

Summary

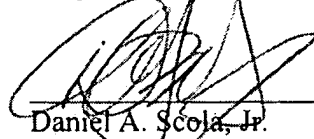
Therefore, Applicant respectfully submits that independent claims 1, 9, 11, 14 and 17, and all claims dependent therefrom, are patentably distinct. This application is believed to be in condition for allowance. Favorable action thereon is therefore respectfully solicited.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

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The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if any, under 37 C.F.R. § 1.17 and also should be treated as a constructive petition for an extension of time in this reply or any future reply pursuant to 37 C.F.R. § 1.136.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Daniel A. Scola, Jr.", is written over a horizontal line.

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Attorney for Applicants

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